

VERMONT AGENCY OF AGRICULTURE, FOOD & MARKETS
FOOD SAFETY CONSUMER PROTECTION DIVISION
Meat Inspection Service
MONTPELIER, VT
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MIS DIRECTIVE

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ENFORCEMENT, INVESTIGATIONS AND ANALYSIS OFFICER (EIAO) FOOD SAFETY ASSESSMENT METHODOLOGY

Part I – General

I. PURPOSE

The purpose of this directive is to provide instructions to EIAOs on how to conduct food safety assessments (FSA) using a new work methodology. This directive also provides instruction on how to document FSAs using the FSA tools, which are a series of questionnaires that EIAOs are to use to gather information, based on the new work methodology. The new work methodology is designed to increase consistency in conducting FSAs and in preparing FSA report documentation for the Public Health Information System (PHIS). This consistency will facilitate analysis of the data that can be derived from FSAs.

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II. CANCELLATION

FSIS Directive 5100.1, Revision 2, Enforcement, Investigation and Analysis (EIAO) Comprehensive Food Safety Assessment Methodology, 7/10/08.

Use of FSIS Form 5000-8 “Comprehensive Assessment of the Execution and Design of an Establishment’s Food Safety System”

III. REASON FOR REISSUANCE

FSIS is reissuing this directive to incorporate the new work methodology to be used by EIAOs when conducting FSAs. This revised directive also includes the FSA tools that EIAOs are to use when documenting findings and making enforcement recommendations.

IV. REFERENCES

[9 CFR 300 to end](#)
[FSIS Directive Library](#)
[Compliance Guide Index](#)

V. BACKGROUND

A. EIAOs are trained to assess the design and validity of food safety systems and to prepare administrative enforcement reports. When performing their duties, EIAOs are acting as authorized representatives of the Secretary of Agriculture and under the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), or the Egg Products Inspection Act (EPIA) (referred to collectively as “the Acts”).

B. EIAOs are to complete FSAs before leaving the establishment. Establishment size, number of Hazard Analysis and Critical Control Point (HACCP) processes employed, and complexity of the assessment will affect the time necessary to complete an FSA. Nonetheless, the EIAO should be able to complete the FSA in 2 to 4 weeks. In the event that an extended amount of time will be needed to complete the FSA, the EIAO is to explain to the District Case Specialist (DCS) and District Office (DO) why the additional time is necessary. The completion of a FSA report should not be delayed for purposes such as to accommodate non-emergency requests for annual or sick leave. Also, in the event that there is a legitimate need to stop an FSA that is already in progress, the EIAO is to communicate with the establishment about the reasons for the delay, and when he or she expects to resume the assessment.

Part II – COMPREHENSIVE FOOD SAFETY ASSESSMENT

CHAPTER 1: METHODOLOGY OVERVIEW: THE FSA TOOLS

I. What are the FSA Tools?

A. The FSA tools are a series of questions that EIAOs are to use when gathering information associated with a specific food safety system component. The tools are arranged by function and include a demographics, recommendation, and background tool; a general sanitation tool; individual HACCP processing category tools; a dual jurisdiction tool; and a food defense tool. EIAOs are to document their findings using the new FSA tools.

B. Every FSA report is to include a completed demographics, recommendation, and background tool; general sanitation tool; and food defense tool if a plant has a written food defense plan. Every FSA report is to also contain a completed HACCP processing category tool for each HACCP process utilized by the establishment. Finally, an FSA report is to contain a completed dual jurisdiction tool if the plant also produces FDA amenable products.

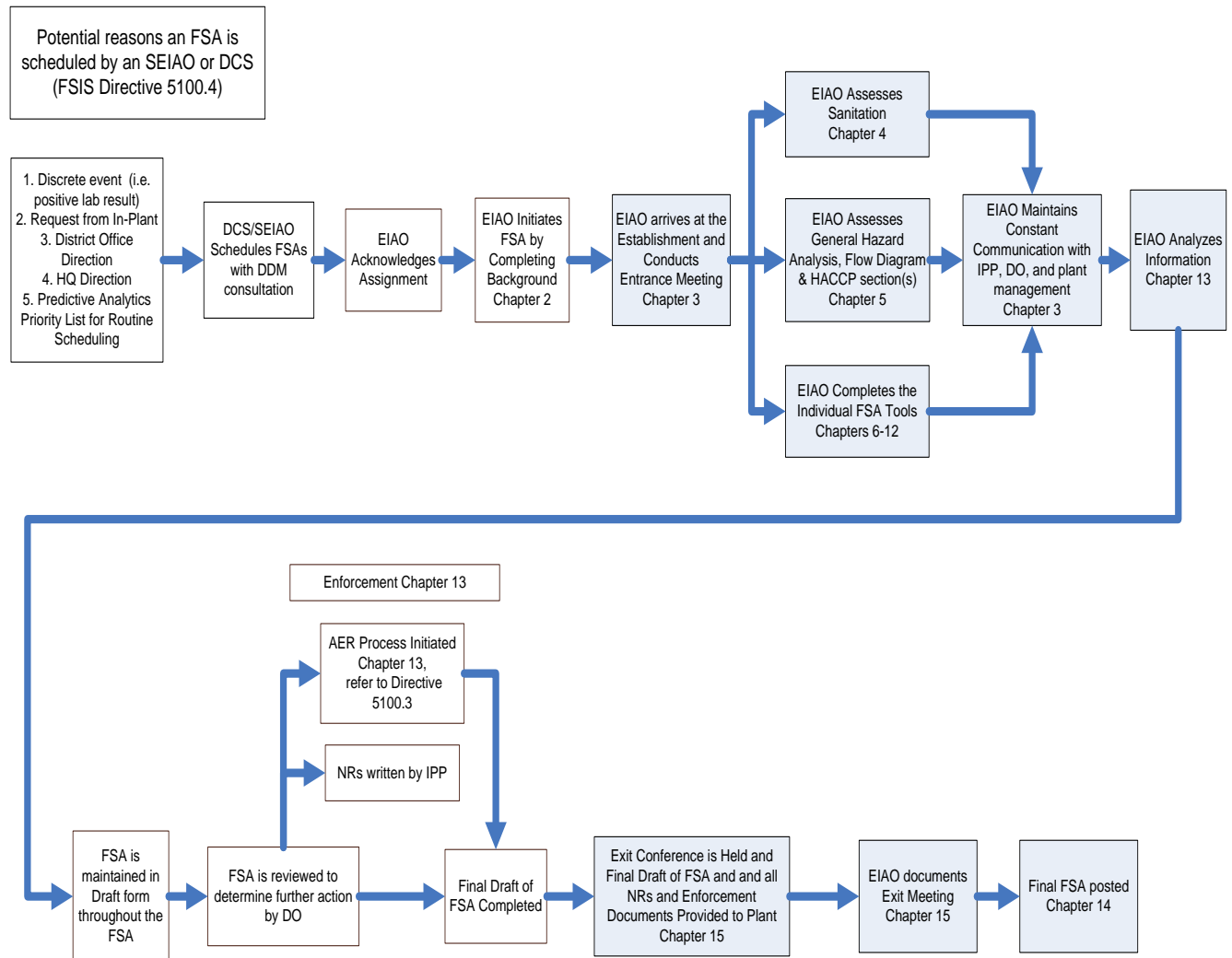
C. The function of the questions in the FSA tools is to provide a structured format for EIAOs to use in gathering the information necessary to analyze the establishment's food safety system. Supplemental information for EIAOs on how to use the questions on microbiological methods is provided in [Attachment 1: Background Information on Laboratory Methods](#).

D. EIAOs are to document their findings as answers to the questions presented. They are then to analyze the answers to reach a logical and supportable recommendation on whether an enforcement action is warranted with respect to the HACCP process.

E. EIAOs are to document their analysis of their findings (answers to the questions). They are to discuss, in particular, the findings that bear most directly on the recommendation that they are making at the end of each individual tool with respect to what action, if any, is appropriate with respect to the establishment's HACCP plans. EIAOs are to summarize these analysis sections in the Executive Summary section.

F. EIAOs are to conduct the assessment through a review of records and documentation as well as through direct observation of establishment operations. EIAOs are also to use [askFSIS](#) to obtain expert advice on scientific or technical issues that arise during the course of their investigations.

G. The EIAO Work Flow Process diagram shown below provides a visual depiction of the FSA process. The EIAO is to follow the work method flow diagram shown below as he or she navigates this directive.



II. How are EIAOs to answer FSA tool questions?

A. Each tool is divided into sections that contain a series of numbered questions with letter prefixes that relate to the section title (H1, H2, H3...) and provide the EIAO with space to document findings associated with certain establishment practices. The numbered questions also contain follow-up questions (H1a, H1b, H1c...) providing the EIAO with space to document more detailed information about the establishment practice introduced in the primary question. Follow-up questions are based on the answer to the main question.

B. Questions are provided in yes/no, multiple choice, and free text formats. In addition, almost all yes, no, or multiple choice questions have a follow-up question asking why the EIAO came to a particular decision, what documents or observations the EIAO used to reach that decision, and what regulations support the decision. The follow-up questions are designed to help the EIAO document the thought process he or she employed and support the decision he or she reached. The EIAO is to document any literature references, dates of observations, establishment documents reviewed, and names and position titles of individuals, as appropriate, to support her or his observations and thought processes. These pieces of information allow the EIAO to provide context and to describe the fact pattern and the timing of events.

Example: There is a question in the HACCP section of each individual HACCP processing category tool that asks whether the HACCP plan has monitoring and verification procedures. First, the EIAO is to document that he or she reviewed the respective HACCP plan to determine whether it includes written procedures for performing these activities. In addition, if the respective HACCP plan includes written procedures as required, the next level of documentation is to include whether the monitoring and verification procedures are designed and implemented effectively to measure the critical limits. The EIAO needs to explain his or her findings in such a way that would enable the reader, who is not in the establishment and did not see the establishment in action or view the documents, to get a mental picture of the process that is the subject of the findings and to understand the thought process that underlies those findings.

C. The HACCP regulatory environment gives an establishment great flexibility in determining how and where in its food safety systems to exert control over food safety hazards. Therefore, it would be difficult to include all possibly relevant regulations for every question. It is essential that the EIAO have a thorough working knowledge of the statutes and regulations along with scientific expertise to assess the design and implementation of food safety systems to determine compliance. The EIAO must also be able to integrate and apply his or her knowledge in assessing the unique facts and circumstances that he or she encounters during an FSA. The questions in each FSA tool are designed to provide a framework to make and document findings and are not a replacement for scientific expertise or knowledge of statutes, regulations, directives, and notices. Where possible, this directive contains references to Agency issuances that provide background information associated with a section or specific question but should not be considered the only references necessary.

D. There are questions designed to gather information related to risk. These questions do not lead to a clear compliance determination but will provide insights into an establishment's risk relative to other establishments when information is analyzed by Headquarters (HQ) personnel.

E. The EIAO is to document all findings in the FSA tools and not keep notes outside the FSA tools. In the case of a recommended enforcement action, the EIAO must forward any notes to the DCS for inclusion as evidence in the AER. The FSA tools have been

organized to facilitate a progression of data gathering during the FSA. Answers are to be limited to the question being asked and any compliance determination. Answers are not to include excessive interpretation of the findings that lay out an enforcement recommendation because interpretation of the findings is to be reserved for the Analysis section ([Chapter 13](#)) at the end of each FSA tool. Constructing an FSA report in this fashion will eliminate repetitiveness.

F. The consistent gathering of information using a question format allows HQ to further analyze the data gathered by the EIAO across all establishments. HQ personnel analyze information across establishments to look for trends that inform policy development, assess the effectiveness of existing policies, determine training needs, and guide outreach activities for industry.

CHAPTER 2: PRE-FSA PREPARATION

I. How does an EIAO schedule an FSA with the establishment?

A. When an EIAO is preparing to conduct an FSA, he or she is to:

1. Provide the establishment 1-2 weeks advance notice of the visit;
2. Provide the Inspector-in-Charge (IIC) 1-2 weeks advance notification of the establishment visit;
3. Gain a basic understanding of how the establishment is operating and of any issues needing particular attention during the course of the FSA. To do so, the EIAO is to communicate with the in-plant inspection team and the meat inspection office to discuss the upcoming FSA and to gain a sense of the establishment's operating practices prior to the entrance meeting with establishment officials.
4. Contact the Supervisory EIAO (SEIAO) to correlate about issues and to discuss the strategy for conducting the FSA.

B. An exception to the 1 – 2 week advance notice would be a “for cause” FSA. A “for cause” FSA is defined as an FSA prompted by knowledge of positive sample results, potential production and shipment of adulterated products, or any other high priority food safety related incident. (See [FSIS Directive 5100.4, Prioritized Scheduling of FSAs](#))

II. How does an EIAO gather and review background information before the FSA begins?

A. The EIAO is to review 6 - 8 months of inspection data before visiting the establishment. The EIAO is to review all relevant data to determine whether there are

patterns or trends that should be investigated upon visiting the establishment. The types of data to review include:

1. PBIS data;
2. Notes of Weekly Meetings;
3. Consumer complaints;
4. Recall information;
5. Establishment compliance history including all NRs issued to the establishment within the last 6-8 months and any establishment responses to NRs;
6. Any FSAs completed at the establishment;
7. Available enforcement data including deferral and abeyance actions, verification plans, and any other correspondence; and
8. Laboratory results including sub-typing information (serotype, PFGE)

B. The EIAO is to review relevant policy issuances (Federal Register Notices, directives, notices, and Agency guidance documents) that pertain to the processes used by the establishment.

C. The EIAO is to review available training materials on general processing principles, guidance documents, and other documents associated with the HACCP processes utilized in the establishment to ensure that the EIAO has a basic knowledge of the processes he or she expects to see at the establishment.

D. During the FSA, the EIAO is to include the pre-visit background data, and the findings documented during the FSA, in his or her analysis of the food safety system to arrive at an enforcement recommendation. Combining these data in the analysis can establish a history of compliance and provide additional context to the FSA findings.

E. The EIAO is to use the Demographics, Recommendation, and Background Tool, to document basic information about the establishment, the reason for the visit, enforcement recommendations, the executive summary supporting the recommendation, and background inspection information. The Demographics, Recommendation, and Background Tool replaces FSIS Form 5000-8 "Comprehensive Assessment of the Execution and Design of an Establishment's Food Safety System."

F. The EIAO is to obtain and analyze 6-8 months of background inspection activity and sampling results to determine whether there are any trends that need further investigation during the FSA.

CHAPTER 3: ESTABLISHMENT ARRIVAL, ENTRANCE MEETING, and ON-GOING COMMUNICATION

I. What activities does an EIAO perform upon arrival at the establishment and during the entrance meeting?

A. The EIAO is to hold a pre-entrance meeting with the in-plant inspection team to discuss existing establishment conditions, prior to meeting with establishment officials.

B. When the EIAO arrives at the establishment, he or she is to conduct an entrance meeting that is to be attended by the in-plant inspection team, and establishment officials. During the entrance meeting, the EIAO is to explain the purpose of the comprehensive food safety assessment, explain why the plant was chosen, and answer questions about the overall process. The topics that the EIAO is to discuss during the entrance meeting include, but are not limited to:

1. An explanation of what a comprehensive food safety assessment is, and how it differs from the day-to-day verification activities that are performed by in-plant inspection program personnel (IPP);
2. A discussion of the EIAO's typical work schedule during the assessment, including how other activities may impact the EIAO's schedule;
3. A discussion of how the EIAO will access the production floor. The EIAO is to inquire whether the establishment has in place any special procedures and request that he or she be given access to those procedures;
4. A discussion of where the EIAO will conduct her or his work. The EIAO is to ask where the establishment stores its records and ask that he or she be given access to examine and copy or scan any records that may be needed to support non-compliance determinations made during the course of the review;
5. An explanation that the EIAO's role is not to resolve disputes between the establishment and IPP;
6. An explanation that the EIAO will communicate with the in-plant inspection team and establishment management about findings as the assessment progresses;
7. A discussion of the possible FSA outcomes and an explanation that, if the FSA results in a Notice of Intended Enforcement (NOIE) or suspension, the EIAO will work with IPP to develop a verification plan;
8. An explanation that, at the conclusion of the FSA, an exit conference will be held with establishment officials; and

9. An explanation that once the FSA is complete, the establishment will be provided a draft copy of the FSA report. The EIAO should also advise the establishment that once a final copy of the FSA report is prepared, it will also be provided to the establishment.

C. The EIAO is to use the [Demographics, Recommendation, and Background Tool](#) to document the entrance conference. The EIAO is to include a description of the entrance conference, including the date, participants, and the topics discussed.

II. How is an EIAO to communicate with interested parties during an FSA?

A. The EIAO is to communicate with the establishment throughout the course of the assessment and inform establishment management about any findings of regulatory non-compliance as soon after finding them as possible. The EIAO is to describe to establishment management, in clear terms, any non-compliances and weaknesses that he or she identifies as the assessment progresses. During the course of the assessment, the EIAO is not to predict possible outcomes of the FSA.

NOTE: An establishment's attempt to bring itself into compliance upon being notified of a non-compliance finding during the FSA does not negate the non-compliance. All non-compliances are to be documented in the FSA by the EIAO and in noncompliance records (NRs) by IPP. If an enforcement action is recommended, relevant non-compliances are to be documented in the NOIE or suspension letter.

B. The EIAO is to communicate with the in-plant inspection team throughout the course of the assessment, describing the noncompliances and weaknesses that he or she has identified.

1. The EIAO is to communicate with the in-plant inspection team about the team's observations and experiences pertaining to the establishment's production practices.
2. In the event that the inspection personnel provide information to the EIAO that has a bearing on an enforcement recommendation, and this information is not already documented in NRs or in notes of weekly meetings with the establishment that are being used as evidence, the EIAO is to describe the information obtained in the FSA report.
3. The EIAO and the in-plant inspection team are to work collaboratively to ensure that all non-compliances are communicated to establishment management and documented for issuance during the exit meeting. Thus, in the event that the EIAO decides to recommend that the in-plant team issue NRs, the EIAO is to work collaboratively with the IIC and in-plant team to ensure that the NR is written and issued to establishment management.

4. During the assessment process, the EIAO is to provide frequent updates to the SEIAO on the progress of the FSA and the strategy for moving forward. The EIAO is also to provide frequent updates to the IIC to inform them of the EIAO's findings and of any recommendations that the EIAO is planning to make.

III. Why is proper communication important?

A. The EIAO is to carry out his or her duties in a fair, firm, professional, and courteous manner; treat in-plant and establishment personnel with respect; and keep them informed as to his or her actions by maintaining open lines of communication. How the EIAO conducts himself or herself plays a key role in the success of the assessment. The EIAO is to work cooperatively with the in-plant inspection team and with establishment officials to effectively perform her or his duties.

B. The EIAO is to request information, not demand it, and be able to explain to establishment officials the statutory authority under the FMIA, PPIA, and EPIA to examine facilities and to copy records. In the event that the EIAO encounters uncooperativeness or unwillingness of establishment officials to provide information, the EIAO is to communicate with the Supervisory EIAO (SEIAO) to develop a strategy for gaining access to necessary information. The SEIAO is to contact the Agency's legal counsel and the issuance of an administrative subpoena to obtain such records if necessary because of continued establishment uncooperativeness.

C. Information gained during the FSA is to be used to inform the Agency about risks existing at the establishment and in aggregate analyses, to inform inspection verification resource distribution and policy development across establishments. Effective communication facilitates gathering this information.

D. EIAOs are to conduct themselves as model food safety professionals at all times. They are to display personal integrity, respect for others, and a commitment to excellence, while carrying out their role of protecting public health.

CHAPTER 4: GENERAL SANITATION: SPS and SSOP

I. How does an EIAO assess establishment's compliance with SPS and SSOP requirements?

A. [FSIS Directive 5000.1](#), Verifying an Establishment's Food Safety System, describes the IPP's responsibilities for verifying that an establishment's food safety system is adequate. The EIAO is to use the policy information in FSIS Directive 5000.1 as a guide for answering the questions in the General Sanitation tool. The goal of these questions is to provide a framework for the EIAO to use in systematically gathering information to determine whether the establishment's food safety system is adequately designed and implemented to prevent the creation of insanitary conditions or direct product contamination. The EIAO is to review food safety system records and documents, in combination with direct observation of establishment conditions and sanitary practices, to answer the questions in the tool to develop an enforcement recommendation.

B. EIAO Assessment of Sanitation Performance Standards (SPS)

1. The SPS regulations do not require establishments to maintain records associated with the SPS requirements. Because there is no design requirement in these regulations, the EIAO uses his or her observation skills to determine compliance. During the initial data assessment, the EIAO is to review and consider NRs issued under 06D01 and how they reflect on the plant's ability to execute its food safety system. Also, if an establishment is consistently failing the *Salmonella* performance standards, the EIAO might be asked to assess whether the establishment is complying with the SPS regulations.
2. In performing this assessment, the EIAO is to be aware of any problems in complying with the SPS requirements that could be having an impact on food safety. For example, if the EIAO found that employee hygiene and product handling practices were not meeting the regulatory requirements, this failure could be having a direct impact on an establishment's ability to meet the *Salmonella* performance standards.
3. SPS compliance can also have an impact on the HACCP system. For example, if the establishment is reusing water and has not considered the impact of the reuse water on the product, the EIAO may find that there is a hazard that is not being addressed by the establishment.
4. The EIAO is to consider his or her findings related to the sanitation programs in context with all of the other food safety systems at the establishment.
5. When making a determination of regulatory compliance and process control, the EIAO is to view the operation in its entirety. Proper implementation of sanitation

measures by establishment personnel is essential to producing safe, wholesome and unadulterated product. Therefore, the EIAO, as part of the FSA, is to directly observe establishment operations in the implementation of its sanitation measures to determine whether the establishment is able to maintain an adequate level of sanitation to prevent the direct contamination or adulteration of product.

C. EIAO Assessment of Sanitation SOPs Prerequisite Programs

1. The EIAO is to systemically review the design, and to observe implementation of the establishment's Sanitation SOPs. The EIAO is to review the Sanitation SOP and pre-operational and operational sanitation records for at least the preceding 60 days and answer questions contained in the general sanitation tool.
2. While the SPS requirements define general objectives the establishment needs to accomplish to maintain sanitary conditions and prevent product adulteration, the Sanitation SOP requirements focus on the routine procedures performed before and during operations that prevent direct product contamination or adulteration.
3. The EIAO is to assess whether the Sanitation SOPs are designed and implemented in a manner to prevent direct product contamination or adulteration.
4. In performing this assessment, the EIAO is to analyze how problems in complying with Sanitation SOP requirements affect the establishment's ability to support decisions in its hazard analysis or to implement its HACCP plan effectively. For example, if a slaughter establishment is having positive pathogen sampling results or failed zero tolerance checks, the EIAO is to question whether the Sanitation SOPs are designed to prevent direct product contamination or adulteration, and, therefore, whether the decisions in the hazard analysis using the Sanitation SOPs are fully supported.

[General Sanitation FSA Tool](#)

CHAPTER 5: GENERAL HAZARD ANALYSIS, FLOW DIAGRAM AND HACCP

I. What is the goal of the general hazard analysis, flow diagram and HACCP section of each HACCP processing category tool?

[FSIS Directive 5000.1](#), Verifying an Establishment's Food Safety System, describes the IPP's responsibilities for verifying that an establishment's food safety system is adequate. The EIAO is to use the policy information in FSIS Directive 5000.1 as a guide to answering the questions in this section of each HACCP processing category tool for each HACCP process utilized by the establishment. The goal of these questions is to systematically gather information to determine whether the

establishment's HACCP system is adequately designed and implemented to prevent the production of unsafe products.

II. How does the EIAO assess the establishment's hazard analysis?

A. A thorough, well-supported hazard analysis is an essential foundation for the entire HACCP system since the hazard analysis provides a basis for determining critical control points (CCPs) in the HACCP plan.

B. A hazard analysis is conducted using a two step process: hazard identification and hazard evaluation. During the hazard identification stage, an establishment develops a list of potential hazards by reviewing information about the process. During the hazard evaluation stage, an establishment evaluates those hazards using scientific information in conjunction with knowledge of the establishment's process to determine those hazards reasonably likely to occur. The hazard analysis should also identify how those hazards reasonably likely to occur will be controlled in the HACCP plan.

C. Establishments are required to consider food safety hazards in three broad groups (biological, chemical, and physical) that may occur before, during, and after entry into the establishment (9 CFR 417.2(a)(1)).

1. Examples of biological hazards include bacteria, viruses, and parasites;
2. Examples of chemical hazards include chemicals prohibited in foods or beyond limits allowable in foods, toxins of microbial origin, allergens, specified risk materials (SRMs), pesticides, antibiotics, and hormones; and
3. Examples of physical hazards include glass, wood, metal fragments from equipment, needles, bullets, shot, wires, clips, and twist ties.

D. Establishments need to support the decisions they make in their hazard analysis. An establishment may use various forms of scientific information to support that a hazard is not reasonably likely to occur, and that a prerequisite program will prevent a hazard from being likely to occur.

E. A hazard analysis that is not conducted correctly and that does not identify the hazards warranting control within the HACCP system will cause the HACCP plan to be ineffective regardless of how well the plan is followed. Therefore, flawed (9 CFR 417.2(a)) or unsupported (9 CFR 417.5(a)(1)) hazard analyses may be cause for the EIAO to call the validity of the entire HACCP system into question (9 CFR 417.6).

F. The EIAO is to start his or her review of the HACCP system, using her or his scientific knowledge, knowledge of Agency issuances, and professional expertise, by verifying the hazard analysis. The EIAO is to assess whether the establishment has addressed hazards commonly associated with a process, and whether it can adequately support the decisions it made regarding those hazards. The questions the EIAO may

seek answers to when reviewing the hazard analysis are included in the general hazard analysis, flow diagram and HACCP section of each HACCP tool.

NOTE: Processing aid determinations are made by FSIS for the purpose of labeling only and, therefore, should be adequately addressed in the hazard analysis. EIAOs are to verify that processing aids that are described as providing control for a food safety hazard are correctly documented as such in the hazard analysis.

III. How does the EIAO determine if the prerequisite programs are adequate?

A. Since establishments often use prerequisite programs to support decisions in their hazard analysis (e.g., to support that potential hazards are not reasonably likely to occur because they are prevented by a prerequisite program), the EIAO is to gather information carefully on prerequisite programs, assess whether the prerequisite programs support decisions made in the hazard analysis, and determine whether there is compliance with 9 CFR 417.5(a)(1) and 9 CFR 417.2(a).

B. Prerequisite programs are conditions and practices that provide the basic environmental and sanitary conditions that are necessary for the HACCP plan to operate effectively leading to the production of safe and wholesome food. The programs provide a foundation for the development and implementation of an effective HACCP system. They frequently function across product lines and are often managed as facility-wide programs rather than being process or product specific. Typically, prerequisite programs can be implemented without operating the actual process itself since prerequisite programs provide the basic conditions and environment for the process. For example, a processing room's cleanliness and appropriate temperature can be maintained without actually producing product. An establishment can also receive raw materials without producing product. CCPs, however, need the process operating and product being produced to be effectively implemented.

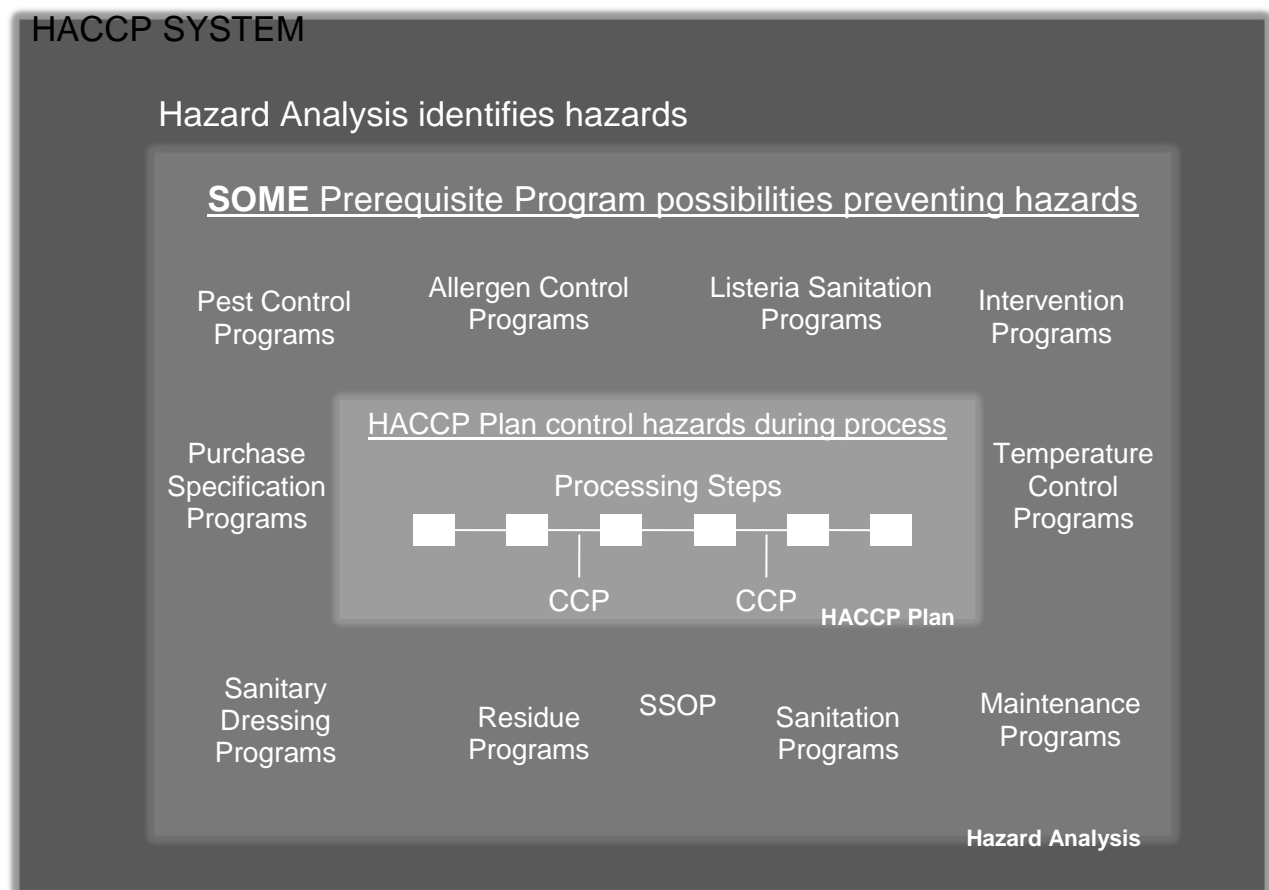
NOTE: Establishments may have unique names for their various prerequisite programs without incorporating "prerequisite" in the title. Temperature control programs, allergen control programs, *Listeria* sanitation control programs, and purchase specification programs are some examples.

C. In the hazard analysis (9 CFR 417.2), an establishment may determine that a hazard is not reasonably likely to occur because the ongoing execution of a prerequisite program prevents the hazard from occurring. This is different from determining that a hazard is reasonably likely to occur in the process in the absence of controls (i.e., critical control points (9 CFR 417.2)) that prevent the hazard, eliminate it, or reduce to an acceptable level the likelihood of its occurrence.

D. The EIAO is to be aware that prerequisite programs cannot be used as the direct means to control a hazard during the process. Deviations from a prerequisite program may call into question whether decisions in the hazard analysis are adequately supported, and whether identified hazards are being prevented by the prerequisite program. A food safety concern would arise if there were deviations in the prerequisite

program resulting in a hazard that is not addressed or controlled by the HACCP plan. Purchase specification prerequisite programs are an example of how a deviation could lead to a food safety concern. By not adhering to the prerequisite program, a hazard is not prevented, and therefore the HACCP plan would not be designed to control the hazard, leading to the failure of the HACCP system.

E. The hazard analysis provides the framework for the design of prerequisite programs and the HACCP plan. Prerequisite programs provide a foundation for the HACCP plan to operate effectively. The diagram below is an illustration of how the HACCP system is built. The outer layer, which contains various types of prerequisite programs that may be used, provides the foundation for the decisions made in the hazard analysis. The HACCP plan itself is in the center of the diagram because the hazard analysis and the prerequisite programs provide the underpinnings for the process to operate effectively.



F. In order to make a determination as to whether a prerequisite program is appropriately designed to prevent a hazard according to decisions made and supported in the hazard analysis, or whether the program is being used to control a hazard and therefore requires a CCP in the HACCP plan, the EIAO should seek answers to the following questions.

1. If the critical parameters listed in the prerequisite program are not met, are there questions concerning the safety of the product?
2. If the critical parameters listed in the prerequisite program are not met, does the establishment implement corrective actions that meet the requirements of 9 CFR 417.3?
3. Is historical information the only support for the use of the prerequisite program and does that information show that the prerequisite program is sometimes ineffective in preventing the hazard, thereby creating the need for a CCP in the HACCP plan?
4. If the answers to such questions are yes, then it is probable that the prerequisite program is being used to control the hazard. The EIAO is to discuss such findings with the establishment and is to inform the establishment that it needs to reassess its HACCP plan to reconsider the use of the programs and to properly address the hazards. The failure of the establishment to do so may result in FSIS issuing a NOIE.

G. Since prerequisite programs form the basis of decisions in the hazard analysis, the EIAO is to review the features of the prerequisite program, including supporting documents and validation information that the establishment has for the parameters in the program. If the EIAO finds that the prerequisite program is ineffective or is not being executed as designed, or that the establishment does not maintain on-going verification records, the EIAO is to advise the IIC to issue an NR to the establishment because its hazard analysis is inadequate. The establishment would need to reassess its hazard analysis (9 CFR 417.4). See [Chapter 13](#) for further instructions.

H. The EIAO is to review at least 60 days of data reflecting how the program has operated over a recent time-period and consider whether it seems to be successful. The EIAO is to assess whether the records support that the hazard is not reasonably likely to occur because of the use of the prerequisite program. To do this review, there needs to be documentation outlining the procedures of the prerequisite program and on-going verification data demonstrating consistent implementation.

I. Yearly letters of guaranty or once per year third party audit information as part of purchase specification prerequisite programs do not constitute on-going verification.

Ongoing verification involves consistent data gathering throughout the year to verify that the parameters described in the purchase specification continue to be met.

J. If sampling and testing are part of the prerequisite program, the EIAO is to use the [Attachment 1, Background Information on Laboratory Methods](#), to review the establishment's microbiology method documentation. EIAOs can seek help through [askFSIS](#) to get assistance in reviewing these documents by categorizing their question as "Sampling" within the *askFSIS* system. Examples can include sampling of incoming raw materials or food contact surfaces and environmental surfaces to verify sanitation. For example:

- If an establishment is producing raw ground beef products and has a prerequisite program based on compliance with raw material purchase specifications, the EIAO is to review the records (design and implementation) associated with such a prerequisite program to verify that the documentation supports the decision made in the hazard analysis that *E. coli* O157:H7 is not reasonably likely to occur.
- If the establishment is producing RTE products and has included food contact surface or environmental testing in a prerequisite program, the EIAO is to review the prerequisite program to verify that it is science-based. The EIAO is to assess the establishment's total HACCP system to verify that the establishment has designed its testing procedures to find the indicator organisms or *L. monocytogenes* if present, and the establishment has procedures in place within its HACCP system to effectively address their presence if detected. The EIAO is to review written procedures, assess decision-making documents for rationale, and review laboratory results.

K. An ineffective prerequisite program results in a hazard being reasonably likely to occur because the hazard is not accounted for in the hazard analysis. Since the prerequisite program is ineffective and not preventing the hazard, there is noncompliance with 9 CFR 417.5(a)(1) and 417.2(a). The establishment would need to reassess its hazard analysis, 9 CFR 417.4, to determine whether any modifications to the hazard analysis are necessary and make those changes to address the hazard. In addition, the HACCP system may be inadequate, 417.6, and result in the EIAO recommending an NOIE.

L. Some prerequisite programs may be linked to other prerequisite programs and in essence support a decision in the hazard analysis through their relationship to one another. For example, many establishments use prerequisite programs to support their Sanitation SOP programs, and then only the Sanitation SOP is referenced in the hazard analysis as the relevant prerequisite program.

IV. How does the EIAO assess monitoring requirements?

A. The EIAO performs data collection and analysis to verify that the establishment's monitoring procedures, and the frequency with which it performs those procedures, are adequate to determine whether the critical limits for each CCP are being met.

B. The EIAO is to review the HACCP plan, associated supporting documentation, and a minimum of 60 days of monitoring records to answer the questions in the general hazard analysis, flow diagram and HACCP section of each HACCP processing category tool about the establishment's monitoring procedures and frequencies. The EIAO can review more records anytime she or he decides it is necessary to do so to determine whether there is regulatory compliance.

V. How does the EIAO assess verification requirements?

A. The establishment needs to have implemented verification procedures that are capable of demonstrating that the plan is adequately controlling hazards associated with the product, and that the HACCP system is operating according to the plan. The EIAO is to determine whether an establishment's on-going verification activities comply with regulatory requirements by focusing on the design and execution of these verification activities.

B. The EIAO is to review the HACCP plan and records that cover a minimum of 60 days of activity. The EIAO is to review verification records associated with CCPs. The EIAO is to review documents used to justify the selection of these procedures and the frequency of their performance and then is to answer the analytic questions contained in the general hazard analysis, flow diagram and HACCP section of each HACCP processing category tool.

VI. How does the EIAO assess recordkeeping requirements?

A. Records are evidence prepared to document the results of some kind of action. Recordkeeping ensures that written evidence is available for review. Establishments are to maintain records in the manner, and retain them for the time, as defined in 9 CFR 417.5. The EIAO is to ask establishment management for access to the HACCP records to answer the questions in the general hazard analysis, flow diagram and HACCP section of each HACCP processing category tool.

B. The EIAO is to review the establishment's HACCP records, as specified in 9 CFR 417.5(a)(3), that cover a defined recent period of time. Specifically, the EIAO is to select records from at least the last 60 days of activity to verify the establishment's compliance with recordkeeping requirements.

C. The EIAO is to conduct an assessment of the hazard analysis, HACCP plan, scientific, regulatory, technical, or other supporting documentation as required in 9 CFR 417.5(a)(1) and (2).

VII. How does the EIAO assess corrective action requirements?

A. Corrective actions (9 CFR 417.3) are a key element of the HACCP system because a deviation from a critical limit or an unforeseen hazard could lead to adulterated product being released into commerce. If a HACCP plan is properly designed and implemented, the establishment will discover any deviations and initiate appropriate corrective actions before any product leaves the facility.

B. The EIAO is to review the HACCP plan and select records from at least 60 days of activity to assess the design of the corrective actions, to discover deviations or unforeseen hazards, and to verify that the establishment met all parts of corrective actions when required. If corrective action requirements were not triggered during the last 60 days of operation, the EIAO is to attempt to find the last instance in which a corrective action was taken, so that he or she can verify that the establishment met the corrective action requirements.

C. During the assessment of the records, the EIAO is to seek answers to the questions verifying the corrective action requirements in the general hazard analysis, flow diagram and HACCP section of each HACCP processing category tool.

D. Additional corrective action questions are placed throughout the individual FSA tools to assist in the thought process of assessing the adequacy of corrective action procedures.

VIII. How does the EIAO assess reassessment requirements?

A. Under the reassessment requirements in 9 CFR 417.4(a)(3), establishments are to reassess their HACCP plans at least annually, or whenever any changes occur that may affect the hazard analysis or alter the HACCP plan.

B. The EIAO is to review a minimum of 60 days of records to determine whether a situation occurred that should have triggered a reassessment of the hazard analysis or HACCP plan.

C. If the establishment did do a reassessment, the EIAO is to review the determinations the establishment made, and any actions it took based on the reassessment.

D. The EIAO is also to verify that the establishment met the annual reassessment requirement. Refer to [FSIS Directive 5000.1](#) for more information.

IX. How does the EIAO assess validation requirements?

A. 9 CFR 417.4 requires that each establishment initially validate the adequacy of its HACCP system in controlling those food safety hazards identified in its hazard analysis.

B. Validation has two parts:

1. The first part is the scientific or technical justification for interventions used as part of the food safety system (i.e. supporting documentation that may include scientific articles, manufacturer specifications, challenge studies, or pathogen modeling data).
2. The second part is the in-plant validation. This second part requires that the establishment demonstrate that it can effectively implement the interventions within its process and achieve the same level of control as the supporting documentation to validate the entire food safety system. An establishment is to review records generated as part of the food safety system's operation, including microbiological data where appropriate, during the initial validation period (90 days).

C. Examples of HACCP system elements that need validation include CCPs and prerequisite programs, such as purchase specification programs or product formulations.

D. The scientific support and initial in-plant validation documents are supporting documentation records according to 9 CFR 417.5(a)(1) and, therefore, are to be kept for the life of the HACCP system. These records support the food safety decisions made in the hazard analysis.

E. There are validation questions in the general hazard analysis, flow diagram and HACCP section and in the "Intervention and Validation" section of each individual HACCP Category tool.

CHAPTER 6: RAW MEAT PROCESSING CATEGORIES (03J, 03C, 03B MEAT)

I. Why are sanitary dressing practices and process control crucial to an establishment's ability to produce safe, wholesome and unadulterated product?

Effective sanitary dressing procedures and process controls provide the basis for the critical control points (CCPs) that prevent, eliminate, or reduce to an acceptable level food safety hazards in the meat slaughter and other raw meat processes (see [FSIS Directive 6410.1](#), Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age). While conducting the FSA at a cattle slaughter establishment, EIAOs are to spend time on the kill floor observing and assessing the sanitary dressing practices and then document their observations in the FSA report. They are to discuss with the FLS and the IPP what they observe regarding the establishment's sanitary dressing and process control practices. In the event that information, such as NRs, weekly meeting notes or other information provided by the FLS or IPP, supports an enforcement recommendation, the EIAO is to document the

information received in the FSA report. Further, in the event that the decision is made to initiate enforcement then this documentation is to be included as evidence in the AER.

II. How does an EIAO assess meat slaughter processes?

A. The EIAO is to verify, using the 03J Meat Tool, that establishments slaughter livestock in a manner designed to prevent contamination from occurring at any step in the process, and that establishments use decontamination and antimicrobial interventions as necessary to address any contamination or cross contamination that may result from the process or otherwise may occur on the carcasses (9 CFR 310.18).

B. [FSIS Directive 6420.2](#) describes the IPP responsibilities for verifying that a slaughter establishment is controlling fecal material, ingesta, and milk. The EIAO is to use the policy information in FSIS Directive 6420.2 in answering the questions in the 03J Meat Tool.

C. The slaughter of beef raises unique verification responsibilities which are contained in the Beef, Sampling and Testing, and SRM sections of the tool. The EIAO is to carefully assess an establishment's controls for *E. coli* O157:H7 and SRMs.

1. The EIAO is to use the policy information in [FSIS Directive 6410.1](#) to answer the questions related to sanitary dressing practices for beef slaughter operations. In the absence of written procedures and records documenting the implementation of sanitary dressing procedures, the HACCP system likely would not be adequate to control food safety hazards.
2. The EIAO is to use the policy information in [FSIS Directive 6100.4](#) to answer the questions related to SRMs for beef slaughter operations.

D. When making determinations of regulatory compliance and process control, the EIAO is to consider how all the information gathered relates to the overall system, including sanitary practices; antimicrobial interventions; effectiveness of microbial testing on products and equipment; and adequacy of employee training for assignments at particular points in the process. Appropriate performance by establishment personnel is essential for adequate process control. Therefore, the EIAO, as part of the FSA, is to observe establishment operations in the production of product to determine whether the establishment is able to implement its written HACCP plan, SSOP, pre-requisite programs, and GMPs effectively.

03J Slaughter Meat Tool

III. How does an EIAO assess raw meat processing?

A. Process control is crucial to an establishment's ability to process raw meat products. The 03B Raw Ground and 03C Raw Not Ground Meat Tools will assist EIAOs in gathering pathogen control information on the establishment's processing procedures

as well as on its sanitation and HACCP system to verify the effectiveness of the establishment's food safety system.

B. EIAOs are to verify whether establishments are properly addressing *E. coli* O157:H7 in their food safety systems for raw beef products.

1. EIAOs are to use information in [FSIS Directive 10,010.1](#) when assessing establishments that produce non-intact raw beef products or intact raw beef products intended for use in non-intact raw beef products, as he or she answers the questions in the 03B and 03C Meat tools.
2. EIAOs are to use the guidance information in [Attachment 1](#) when reviewing microbiology methods to answer sampling questions in the tool. This information is to be used when assessing any purchase specification prerequisite program that includes testing or test results and any finished product testing program.
3. EIAOs are to critically assess any purchase specification prerequisite program to determine whether the establishment can support (9 CFR 417.5(a)(1)) a decision in its hazard analysis (9 CFR 417.2(a)) that *E. coli* O157:H7 is not reasonably likely to occur. Establishments that cannot support decisions in the hazard analysis would be likely to have an inadequate system (9 CFR 417.6). The information provided in Chapter 5 to assess prerequisite programs and the policy information in [FSIS Directive 10,010.1](#) can assist EIAOs in assessing a purchase specification prerequisite program.

C. When making determinations of regulatory compliance and process control, the EIAO is to consider how all the information gathered during the assessment relates to the overall system, including sanitary practices; antimicrobial interventions; effectiveness of microbial testing on products and equipment; and the adequacy of the training of establishment employees for their assignment at particular points in the process. Appropriate performance by establishment personnel is essential for adequate process control. Consequently, as part of an FSA, EIAOs are to observe establishment operations in the production of product to determine whether the establishment is implementing its written HACCP plan or other food safety systems effectively. EIAOs are to also describe their observations in the FSA report and combine this information into an analysis of the findings to reach a compliance decision.

[03C Raw Not Ground Meat Tool](#)

[03B Raw Ground Meat Tool](#)

CHAPTER 7: RAW POULTRY PROCESSES (03J, 03B, 03C POULTRY)

I. Why are sanitary dressing practices and process control crucial to an establishment's ability to produce safe, wholesome and unadulterated product?

A. Effective sanitary practices provide the basis or environment for the critical control points (CCP) that prevent, eliminate, or reduce to an acceptable level food safety hazards that are reasonably likely to occur in the production process. These together provide process control.

B. It is FSIS's expectation that establishments process products in a manner that is designed to prevent contamination from occurring at any step in the process or to use decontamination and antimicrobial interventions as necessary to address any contamination that may occur.

C. These FSA tools provide information describing how the EIAO is to verify that the establishment has designed and implemented a HACCP system, including its sanitation procedures and antimicrobial interventions that it employs as part of its sanitary practices, in poultry slaughter and other raw poultry processes to produce safe, unadulterated products.

II. How does an EIAO assess poultry slaughter and processing?

A. The 03J Poultry Slaughter Tool contains one section of pre-harvest questions when establishments use pre-harvest practices to support decisions in their hazard analysis. Establishments that do not use pre-harvest practices to support decisions in their hazard analysis may choose on a voluntary basis to provide the necessary documents for EIAOs to answer the questions in the pre-harvest section of the 03J Poultry Slaughter Tool.

1. Establishments that do not use pre-harvest practices to support decisions in their hazard analysis are not required to provide any information to answer the pre-harvest section questions. The EIAO is not to use any of the information provided, or the lack of information, as justification for regulatory action unless the establishment uses pre-harvest practices to support decisions in the hazard analysis.
2. The EIAO is to explain to the establishment that providing information for the EIAO to answer these questions enables the EIAO to verify that the establishment incorporates, to the extent possible, pre-harvest interventions in its food safety system. FSIS intends to collect this information in order to populate risk based models to better inform Agency guidance and policies.
3. The EIAO is to consider whether the establishment has a food safety system that is designed to ensure a consistent type of flock entering the establishment in terms of cleanliness, health, and size. The EIAO is also to consider whether the establishment is able to detect and to respond when changes in flock consistency occurs.

B. When making determinations of regulatory compliance and process control, the EIAO is to view the operation in its entirety, from receiving of live birds and raw product

through finished product. Appropriate performance by establishment equipment and personnel is essential for adequate process control. Therefore, the EIAO is to directly observe establishment operations in the production of product, to ensure that any prerequisite programs, Sanitation SOPs, or HACCP plans are implemented as written and are effective at maintaining consistent process control.

C. The EIAO is to assess any testing performed by the establishment on components and final product.

1. The EIAO is to verify that any sampling and analysis methods used by the establishment are validated, appropriate for use, and properly executed by using [Attachment 1](#). The EIAO is to determine whether the establishment identifies positive microbiological samples to the serotype level, and if so, whether it makes changes to its HACCP system based on the sampling results.
2. The EIAO is to determine whether and how the establishment responds to test results that are trending upward.
3. If the establishment is in Category 2, Category 3, or has received positive *Salmonella* test results in previous PR/HACCP sets with serotypes and PFGE patterns of human health concern, the EIAO is to inquire whether the establishment is making or has made, changes to its food safety system to improve its process control, and whether the establishment has assessed whether these changes are effective. EIAOs are to utilize past PR/HACCP Set “end of set letters” to gather information about an establishment’s past PR/HACCP set results. An establishment in Category 3 by definition is an establishment with poor process control, and this fact combined with FSA findings may provide the basis for determining that the HACCP system is inadequate.

[03J Slaughter Poultry Tool](#)

[03C Raw Not Ground Poultry Tool](#)

[03B Raw Ground Poultry Tool](#)

CHAPTER 8: PARTIALLY PROCESSED PRODUCTS (03H)

How does an EIAO assess processes that produce partially processed NRTE products?

A. This series of questions in the 03H Tool are designed to help the EIAO gather information and think through the issues associated with heat treated, not fully cooked, and not shelf stable 03H products. The EIAO is to assess the establishment’s supporting documentation for the decision in its hazard analysis that the product is not-ready-to-eat (NRTE). In addition, the EIAO needs to assess the design of the stabilization process to determine whether these products are properly cooled, whether

the establishment's labels have been approved, and whether any cooking instructions on the label have been appropriately validated.

B. Cooking instructions for heat treated, not fully cooked, and not shelf stable products are crucial because these products are not ready-to-eat, and the cooking instructions are the means by which an establishment can instruct consumers how to render the product safe to consume. Thus, it is essential that any cooking instructions have adequate support and be validated as producing a safe product. EIAOs may refer to the information on [cooking instruction validation](#) for 03H products as they seek answers to the questions in the 03H Tool.

[03H Heat Treated Not Fully Cooked Not Shelf Stable Tool](#)

CHAPTER 9: PROCESSED PRODUCTS (03E, 03F, 03G, 03I and 03D)

I. What are the general considerations when assessing an 03E, 03F, 03G, 03I and 03D process?

A. The HACCP regulations require that establishments have HACCP systems with validated lethality processes that reflect the scientific technical support describing the process, including ingredients. The HACCP regulations also require that establishments implement effectively their HACCP systems to produce safe, unadulterated products.

B. The 03E, 03F, 03G, 03I, and 03D tools provide questions for the EIAO to use in verifying that the establishment has a validated HACCP system producing unadulterated products.

C. When making determinations of regulatory compliance and process control, the EIAO is to view the operation in its entirety (i.e., ingredients, ingredient levels, allergens, equipment, process monitoring, and instrument calibration). Appropriate performance by establishment personnel is essential for adequate process control. Therefore, it is essential for the EIAO, as part of the FSA, to observe establishment operations in the production of product.

D. The EIAO is to verify whether the establishment produces post-lethality exposed RTE products as part of its 03E, 03F, 03G, or 03I processes. Policy information in [FSIS Directive 10,240.4](#) can assist EIAOs in determining whether an establishment produces post-lethality exposed RTE products and are subject to 9 CFR 430. If so, the EIAO is to follow the instructions in [Chapter 10](#).

II. How does an EIAO assess 03E not heat treated, shelf stable processes?

A. For not heat treated, shelf stable products, the primary, product-defining lethality is attained through a non-heat treatment such as drying or fermentation. Some heat may

be applied, but it will not be the primary lethality treatment that defines the overall process. For example, in a dry salami process, the fermentation and drying steps define the process by which pathogens are controlled and the product is identified.

B. Although heat may or may not be applied in the process, it does not define the process or the product. Shelf-stable products are those that do not spoil under ordinary ambient temperature and humidity conditions if package integrity is maintained. These products are free of microorganisms that are capable of growing in or on the product under the non-refrigerated conditions (over 50°F) at which the product is intended to be held during distribution and storage. Products in this category may be salt-cured or fermented and include salami, pepperoni, and ready-to-eat cured hams.

[03E Not Heat Treated Shelf Stable Tool](#)

III. How does an EIAO assess 03F heat treated shelf stable processes?

A. For heat-treated, shelf stable products, the primary, product-defining lethality is attained through heat. The heat step eliminates or reduces to an acceptable level the pathogens of concern such as *Salmonella* or *E. coli* O157:H7.

B. Shelf-stable products are those that do not spoil under ordinary ambient room temperature and humidity conditions if package integrity is maintained. Shelf stability in these products is achieved during the heating or drying process. These products are free of microorganisms capable of growing in or on the product under the non-refrigerated conditions (over 50°F) at which the product is intended to be held during distribution and storage. Products in this category may be dried, fermented, or acidified and include jerky, snack sticks, and pickled pigs feet.

[03F Heat Treated Shelf Stable Tool](#)

IV. How does an EIAO assess 03G fully cooked, not shelf stable processes?

A. Assessing the efficacy of an establishment's interventions, pathogen control programs, and Sanitation SOPs is very important for fully cooked, not shelf stable products. For these products, the primary lethality is attained through heat. In assessing the establishment's food safety system, the EIAO is to determine whether the establishment has considered possible hazards in its hazard analysis, and whether it has put sufficient controls in place to address those hazards. Many of these products are post-lethality exposed and use sanitation measures in addition to not being shelf stable (see [Chapter 10](#)).

B. The EIAO needs to examine carefully the support used for validation of the cook step and the stabilization step as he or she answers the questions in the 03G Tool. For ready-to-eat (RTE) products, he or she also needs to consider whether the sampling

and testing procedures used by the establishment are adequate and meet Agency requirements (see [Attachment 1](#)).

[03G Fully Cooked Not Shelf Stable Tool](#)

V. How does the EIAO assess 03I secondary inhibitors not shelf stable processes?

A. In the production of products with secondary inhibitors that are not shelf stable, the lethality is attained by a process that introduces a substance that reduces the water activity or pH of the product. This substance does not usually kill microorganisms but alters the product in such a way as to inhibit the growth of microorganisms. These products often attain a full lethality by means of a cumulative process using a number of partial lethality processing steps. Processing steps may include heat, drying, curing, fermenting, or adding salt or sugar. Products of this type include country style ham, salt pork, and semi-dry fermented sausages.

B. Since these products attain a full lethality through a cumulative effect, it is essential that the EIAO verify that an establishment has well-documented scientific support and has gathered in-plant data to validate that the process is effective.

[03I Secondary Inhibitors Not Shelf Stable Tool](#)

VI. How does the EIAO assess 03D thermally processed commercially sterile processes?

A. The questions in this tool are designed to assist the EIAO in gathering information about how establishments address the production of thermally processed, commercially sterile products. [FSIS Directive 7530.2](#), Verification Activities in Canning Operations, describes the IPP responsibilities in canning establishments. The EIAO is to use the policy information in FSIS Directive 7530.2 as guidance while answering the questions in the 03D tool.

B. The HACCP system for thermally processed, commercially sterile (canned) meat and poultry products needs to address the physical, chemical, and biological hazards associated with production of this type of product. The establishment can address biological hazards either by implementing the requirements under 9 CFR 318 Subpart G (for meat products) or 381 Subpart X (for poultry products) in their entirety as a prerequisite program or by controlling biological hazards identified in the hazard analysis in its HACCP plan.

C. If the establishment does not use the prerequisite program option of addressing biological hazards through the regulatory requirements of 9 CFR Part 318 Subpart G or Part 381 Subpart X, the establishment is still required to address all canning regulations in its HACCP plan. For example, the establishment could not eliminate canning requirements such as can seam analysis, deviation evaluation, or finished product

inspection in its HACCP plan. Establishments are required by 9 CFR 417.2(c)(3) to ensure that critical limits are set to at least meet minimum applicable FSIS requirements.

D. The 03D tool provides a framework for the EIAO to gather the necessary information to verify that the establishment is properly implementing the requirements in 9 CFR Part 318 Subpart G or Part 381 Subpart X as a prerequisite program or is controlling biological hazards identified in the hazard analysis in its HACCP plan to produce thermally processed commercially sterile products.

[03D Thermally Processed Commercially Sterile Tool](#)

Chapter 10: POST LETHALITY EXPOSED RTE PRODUCT SECTIONS (PLT, AMAP, and SANITATION)

I. How does an EIAO assess processes that produce post-lethality exposed RTE products?

A. On June 6, 2003, FSIS published an interim final rule, “Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products; Final Rule” ([68 FR 34207](#)) that amended its regulations to require official establishments that produce certain RTE meat and poultry products prevent product adulteration by the pathogenic environmental contaminant *Listeria monocytogenes* (*Lm*). In particular, 9 CFR 430.1 sets out the definitions of these terms and 9 CFR 430.4(a) states that *Lm* is a hazard that an establishment producing a RTE product that is exposed to the post-lethality environment needs to control through its HACCP plan or prevent in the processing environment through a Sanitation SOP or some other prerequisite program.

B. The interim final rule also states that RTE product is adulterated if it contains *Lm*, or if it comes into direct contact with a food contact surface that is contaminated with *Lm*. 9 CFR 430.4(b) sets out three alternatives that establishments producing post-lethality exposed RTE product are to choose from in order to meet the requirements of 9 CFR 430.4(a). The EIAO is to verify establishment compliance with the regulatory requirements of 9 CFR Part 430 which may include establishment food contact surface sampling for Alternative 2 Choice 2 and Alternative 3.

C. EIAOs are to verify that, if an establishment is producing any post lethality exposed RTE product using the 03E, 03F, 03G, or 03I processes, it is complying with 9 CFR 430.4. EIAOs are to use the policy information in [FSIS Directive 10,240.4](#), and [FSIS Directive 10,240.5](#) in seeking answers to the questions in the relevant sections to verify an establishment’s compliance with 9 CFR 430.4.

1. EIAOs are to complete the Post Lethality Treatment (PLT) and Antimicrobial Agent or Process (AMAP) section questions of the relevant HACCP processing category tool if an establishment produces any products using Alternative 1.

2. EIAOs are to complete the appropriate section questions of the relevant HACCP processing category tool for establishments that produce products using Alternative 2. Alternative 2 has two choices. The EIAO is to use the PLT section questions of the relevant HACCP processing category tool for an establishment that selects Alternative 2, Choice 1 and uses a post-lethality treatment (which may be an antimicrobial agent) to reduce or eliminate *Lm* on the product. The EIAO is to use the AMAP section questions and Sanitation section questions of the relevant HACCP processing category tool for an establishment that produces post-lethality exposed product and that selects Alternative 2, Choice 2 using an antimicrobial agent or process that suppresses or limits the growth of *Lm* and sanitation.
3. EIAOs are to complete the Sanitation section questions of the relevant HACCP processing category tool for an establishment that chooses to produce any products using Alternative 3.

D. EIAOs are to consider any available establishment and FSIS sampling results for *Lm* or a suitable indicator of *Lm* such as *Listeria* spp. or *Listeria*-like organism when gathering information to answer the PLT, AMAP, and Sanitation section questions. Sampling results may include establishment sampling, FSIS RLM sampling, FSIS IVT sampling, and FSIS RTE001 sampling. Sampling results can be valuable pieces of information when combined with the EIAO's observations and the review of establishment documents. Information gathered in the General Sanitation Tool and prerequisite programs in the General Hazard Analysis, Flow Diagram and HACCP section can be of particular assistance in assessing the establishment's sanitation controls for *Lm*.

E. Further *Lm* positive sub-typing information, such as pulsed-field gel electrophoresis (PFGE), can be helpful in assessing an establishment's food safety system.

1. *Lm* PFGE matches in a single establishment over time or multiple matches of a pattern during a single sampling event, such as an RLM or IVT, may be interpreted as evidence of harborage within the establishment and poor sanitary control. A *Lm* harborage in an establishment can lead to final product adulteration. These matches can be combinations of product, food contact, and environmental positives.
2. PFGE data are generated by the VT Department of Health on all *Lm* positive samples, and matches are confirmed by CDC-PulseNet using pre-determined criteria. When matches are detected, *Lm* PFGE matches are currently reported to the Meat Inspection Office by the VT Dept. of health.

II. What are the important points to consider while assessing post-lethality treatments?

A. PLTs are used to reduce or eliminate *Lm* contamination of post-lethality exposed RTE products.

B. When assessing the effectiveness of a PLT, the EIAO is to examine the establishment's validation to ensure that the PLT is effective in eliminating or reducing *Lm* to an undetectable level before the product is released into commerce. An establishment can use available published research studies as technical scientific support for its PLT. An establishment is also to gather in-plant data to validate the PLT's effectiveness in the establishment's particular product, process, and processing environment.

C. A PLT is to be included as part of the establishment's HACCP plan (9 CFR 430.4(b)(1)(i)).

[Post-Lethality Treatment FSA Tool Questions](#)

III. What are the important points to consider while assessing antimicrobial agents and processes (AMAP)?

A. Antimicrobial agents are substances in or added to the product to eliminate, reduce, or suppress the growth of the *Lm*. Examples include lactates and diacetates added to the product and growth inhibitors in the immediate packaging material.

B. Antimicrobial processes are operations that have the effect of limiting or suppressing the growth of *Lm*. Examples include freezing and reducing the water activity or pH to levels that do not sustain the growth of *Lm*.

C. Antimicrobial agents and processes (AMAP) are used to suppress or limit the growth of *Lm* throughout the product shelf life (i.e., the amount of time the product can be stored under specified conditions and still remain safe with acceptable quality).

D. It is FSIS's expectation that the establishment has scientific technical support documents that validate the AMAP used, and that the establishment implements the AMAP in accordance with the HACCP system and supporting documentation. The procedures in the HACCP system need to reflect the information in the supporting documentation. The establishment is also to gather data demonstrating that it can implement the AMAP as specified in the scientific support. For example, if the antimicrobial agent is applied in a concentration below that specified in the supporting documentation, the antimicrobial agent would likely not achieve the level of control specified in the HACCP plan, unless the establishment can demonstrate with data it developed on site that the antimicrobial does achieve that level of control.

[Antimicrobial Agents and Processes \(AMAP\) FSA Tool Questions](#)

IV. What are the important points to consider while assessing sanitation programs for post lethality exposed processes?

A. All RTE establishments producing post-lethality exposed products are to maintain sanitation in the post-lethality processing environment in accordance with 9 CFR 416.

B. Proper sanitation is crucial to ensure that *Lm* does not form harborage sites and lead to cross contamination of RTE product. Proper sanitation is especially important for an establishment in Alternative 3 because sanitation is the establishment's only control measure for contamination from *Lm*.

C. Sanitation in the RTE processing environment is to be monitored using verification sampling of food contact surfaces in accordance with 9 CFR Part 430.

D. The EIAO is to assess the information gathered in the Sanitation section questions in combination with information gathered in the General Sanitation: SPS and SSOP Tool as well as the hazard analysis information gathered in the General Hazard Analysis, Flow Diagram and HACCP section questions to determine whether sanitation is sufficient to control contamination of product, and whether all possible hazards have been considered.

CHAPTER 11: DUAL JURISDICTION

What additional information should the EIAO consider when assessing dual jurisdiction establishments?

A. The questions in this tool are designed to assist the EIAO in gathering information about whether production practices under FDA (VT Department of Health) jurisdiction affect the establishment's ability to implement effectively its HACCP system under VT State jurisdiction. The VDH and VTAGR cooperate to share information related to dual jurisdiction establishments.

B. The questions in the Dual Jurisdiction Tool address whether the establishment's food safety system is adequately designed and implemented to prevent conditions in the area of the establishment that is only under FDA's jurisdiction from leading to, or creating, insanitary conditions in the FSIS inspected areas of the establishment. The EIAO is to place particular emphasis on those establishments that produce post-lethality exposed RTE products because of the hazard of *Lm* in the processing environment.

[Dual Jurisdiction Tool](#)

CHAPTER 12: FOOD DEFENSE

How does the EIAO complete the Food Defense Tool for establishments with written food defense plans?

- A. The EIAO completes this tool only when she or he has determined that the establishment has a written food defense plan.
- B. The EIAO is to keep in mind that many establishments have procedures in place that support food defense; however, this section is asking only about procedures that are written into a food defense plan.
- C. If the establishment has a written food defense plan but is unwilling to share it with the EIAO, the EIAO is to answer questions G1 and G1a in the tool only.

NOTE: If the establishment does not have a written food defense plan, the EIAO is to document that in the first question and not complete the rest of the questions in the Food Defense Tool.

- D. FSIS has issued “[Developing a Food Defense Plan for Meat and Poultry Slaughter and Process Plants](#),” which is a guide that establishments can use to develop their own food defense plans.

[Link to Food Defense Tool](#)

CHAPTER 13: ANALYSIS AND ENFORCEMENT RECOMMENDATIONS

I. How does the EIAO develop an analysis of the findings?

- A. The function of the analysis question at the end of each tool is for the EIAO to discuss and interpret his or her major findings in light of what is already known about food safety and of how these findings relate to findings in other tools, compliance history, and the regulations to support her or his enforcement recommendation. The EIAO is to explain his or her understanding of the process strengths and weaknesses based on the actual findings, and how these findings bear on the reliability of the food safety system.
- B. Answering the questions in each section of the particular tool is designed to assist the EIAO in gathering the necessary information to analyze and make an assessment of the food safety system and to be able to support that assessment should he or she decide to recommend an enforcement action. The EIAO evaluates the individual findings to find patterns and trends in the information and assesses whether these patterns or trends would lead him or her to determine that the establishment’s process is, or is not, adequate. The EIAO is to use the outcome of this evaluation to answer the final analysis question. The EIAO is to consider the hazard analysis and supporting

documentation, HACCP plan, Sanitation SOP, SPS, and prerequisite program/good manufacturing practice findings in answering the questions below. The following questions are designed to assist the EIAO in making an enforcement recommendation:

1. Is there a relationship between past noncompliance and the noncompliance that the EIAO has observed?
2. Do the findings provide evidence that repetitive, sustained, or persistent food safety problems are occurring?
3. If they do, how long and what information supports this?
4. Is the supporting documentation adequate to support the decisions in the establishment's hazard analysis?
5. Has additional information (e.g., either establishment or FSIS testing) arisen that calls the decisions in the hazard analysis into question?
6. Are there flaws in the design of the system?
7. Can the establishment consistently implement the system as designed?
8. Is there a relationship among the non-compliances the EIAO observed, or can multiple non-compliances be linked together as contributing to a larger food safety concern (often a series of small and seemingly insignificant non-compliances, when linked together, paint a picture of a larger problem within the design and execution of the system)?
9. Does the HACCP system, as designed, prevent the production of unsafe, unwholesome, or adulterated products as required by the FMIA and PPIA?
10. Is there a correlation between testing results and findings related to sanitary practices (through records review and direct observation)?

C. Once the EIAO has analyzed the findings with these questions in mind and has arrived at a supportable enforcement recommendation ("no further action" is considered an enforcement recommendation), the EIAO is to construct a regulatory rationale for his or her enforcement recommendation to guide the analysis writing. An example could be, "The establishment's 03B process is inadequate under 9 CFR 417.6 because the establishment cannot support the decision in its hazard analysis that *E. coli* O157:H7 is not likely to occur." Using the rationale for the recommendation as the main idea of the analysis, the EIAO is to then write a series of coherent paragraphs (usually 3 to 5) with an introductory paragraph, body paragraphs, and a conclusion paragraph discussing the findings that support the enforcement recommendation. The introductory paragraph is to include the rationale and a list of the significant findings that the EIAO plans to discuss in the subsequent paragraphs to support the enforcement recommendation. In

the body paragraphs, the EIAO is to discuss those key findings listed in the introduction and describe how those findings support the enforcement recommendation. In the conclusion paragraph, the EIAO is to summarize how the key findings discussed in the preceding paragraphs support the enforcement recommendation and the impact of the non-compliances on food safety.

D. The FSA report is to present the information in sufficient detail to give the reader a clear understanding of what information the EIAO considered, and of how that information supports the recommendation. As such, when describing documents used to support the recommended action, the EIAO is to include identifying information such as the name and date of the document and other pertinent information necessary to recount the facts. Similarly, if the EIAO obtained pertinent information from establishment or FSIS personnel that has a bearing on the recommendation, the EIAO is to describe what the information is, who provided it, and the date it was discussed with the EIAO. Alternatively, the EIAO is to reference and attach a Memorandum of Interview (MOI) to the FSA report that recounts these facts.

E. When providing a recommendation, in particular, a recommendation to issue a NOIE or suspension, the EIAO is to describe the facts in a manner that makes clear any past noncompliance issues and how they relate to present noncompliance issues. In addition, the EIAO is to include an analysis of the public health and food safety significance of the findings in the report.

F. Similarly, if the EIAO finds noncompliance that would warrant a NOIE or a suspension recommendation, but there is no information that would suggest that multiple or recurring noncompliance has occurred, the EIAO is to explain in the FSA report how the FSA findings establish a basis for concern about the safety of product being produced and why these findings support the recommended enforcement action.

G. If the establishment addresses the deficiencies identified by the EIAO during the course of the FSA, the EIAO is still to document those deficiencies in the FSA and to recommend NRs or enforcement actions as the deficiencies warrant. These deficiencies represent the findings of the FSA whether the establishment addressed them during the course of the FSA or not. Furthermore, it typically requires time to be able to verify the adequacy of corrective actions taken by the establishment in response to the identified deficiencies, to ensure that they are effective. Thus, even if corrective and preventive measures are implemented by an establishment during the course of the FSA, this action should not affect the EIAO's recommendation to issue an NR or to institute other enforcement actions.

H. Additional points to consider when writing the Analysis:

1. FSIS Directives, FSIS Notices, and Compliance Guides are not adequate support for enforcement recommendations;
2. The EIAO is not to simply include a summary of all the FSA findings, but rather, highlight the significant findings that support the enforcement recommendation. “Laundry lists” of findings are not useful and rarely support the rationale for an enforcement action effectively and may reduce the impact of the enforcement recommendation.
3. It is important that the EIAO explain the rationale and the factual basis for her or his enforcement recommendation in a way that would allow a person who never entered the establishment, or who is not familiar with the process, to understand the EIAO’s analysis of the findings and the reasoning for the enforcement recommendation.

I. Information to include in the Analysis

1. Recommending No Further Action

- a. For this recommendation, the EIAO needs to clearly describe the facts gathered that demonstrate that the establishment meets the applicable regulatory requirements, and that no food safety concerns exist.
- b. The EIAO is to describe the documents or other information that he or she considered in reaching this recommendation.

2. Recommending the Issuance of a 30 Day Reassessment Letter

- a. During the FSA, the EIAO may encounter an extremely rare situation where he or she needs additional information to decide whether non-compliance exists (e.g., the establishment needs to clarify how it has supported a determination made in its hazard analysis). In this type of situation, the EIAO is to consult the Meat Inspection office on whether to issue a 30 day reassessment letter.
- b. Typically, when 30 day reassessment letters are issued, the concerns raised relate to the design of the establishment’s HACCP program and do not represent serious food safety concerns. An example may be that an establishment has supporting documentation for a decision in the hazard analysis, but the EIAO needs clarification on how that documentation relates to the process.
- c. A 30 day reassessment letter is not to be issued in lieu of issuing an NR, or where a serious food safety concern requires an enforcement action.

- d. A 30 day reassessment letter is to be written on agency letterhead and clearly focus on the exact clarification needed.

3. Recommending the Issuance of NRs by IPP

- a. The EIAO may recommend that the in-plant inspection team document NRs for non-compliances that do not require an immediate regulatory control action. For example, if an EIAO finds that the establishment has failed to identify a step in the flow chart as required by the regulations, but the situation does not pose an immediate health risk, the EIAO is to document the noncompliance in the FSA and recommend in the FSA that the in-plant inspection team issue an NR. The EIAO is also to notify the FLS and in-plant inspection team of his or her recommendation.
- b. The EIAO is to recommend that NRs be issued only if the noncompliances are not to be used to support the issuance of a NOIE. NOIEs can only reference previous NRs that relate to the cause for the NOIE.
- c. If an EIAO finds non-compliance and plans to use the non-compliance as support for a NOIE, he or she is to only reference the non-compliance in the report and is not to have the inspection team issue an NR. However, it may be necessary for the inspection team to take an appropriate regulatory control action. The EIAO is to explain in the FSA the need for a regulatory control action.

4. Recommending that a NOIE be issued by the DO.

- a. For an EIAO to recommend that the DO issue a NOIE, he or she needs to have information in his or her report that the conditions in the establishment, or the actions of establishment personnel, constitute a situation that would justify the action under 9 CFR 500.4, and that such conditions have resulted in adulterated product or create insanitary conditions that could cause product to be adulterated.
- b. To support such a recommendation, an EIAO is to compile information (e.g., reference previous NRs, noncompliance findings made during the assessment, or a documented trend of noncompliance) and thoroughly analyze that information, reaching a conclusion that an enforcement action is necessary. An EIAO is to use good judgment and only include findings of noncompliance that relate to the basis for the NOIE. An EIAO is not to reference non-related NRs in the NOIE.
- c. Noncompliance found during an FSA unrelated to supporting the NOIE is to be documented in an NR and not included in the NOIE.

- d. When issuing the NOIE, the EIAO is to set out clearly what regulatory requirements have not been met, why the establishment's performance is not adequate, and what information and documentation the EIAO and IPP relied on in making the noncompliance determination. For example, if the EIAO determines that an establishment's HACCP system is inadequate, as provided for in 9 CFR 417.6, the EIAO is to clearly explain in the FSA report how he or she reached that determination, and what specific documentation or information he or she relied upon in making that determination. The FSA findings are to describe what specific facts led to the conclusion. When describing the documentation that he or she is relying upon, the EIAO is to include pertinent information such as the date and name of the document and an explanation of how the document impacts the establishment's system.
 - e. The EIAO is to follow the procedures outlined in [FSIS Directive 8010.3](#), Procedures for Evidence Collection, Safeguarding and Disposal.
5. Recommending a Withholding or Suspension without a NOIE
- a. If the establishment is shipping or producing adulterated product, operating without a HACCP plan, treating animals in an egregious inhumane manner, or engaging in any other type of noncompliance that supports taking a withholding or suspension action without prior notification (9 CFR 500.3), the first obligation of the EIAO is to stop the wrongful practice.
 - b. The EIAO is to notify the FLS and work with the in-plant inspection team to take appropriate regulatory control action, notify establishment officials of the withholding or suspension without a NOIE, and document the basis for the action in a Notice of Suspension.
 - c. The EIAO is to correlate with the in-plant inspection team, to document the facts of the situation. These facts serve as the basis for the withholding or suspension actions that the EIAO has taken, and the EIAO is to document them as evidence.
 - d. In the event that while an FSA is in progress, the Agency takes a withholding or suspension action at the establishment, the EIAO is also to correlate with SEIAO about whether and when to resume and complete the FSA.

II. How does the EIAO write an Executive Summary?

A. The Executive Summary is a brief overview of the FSA report designed to give readers a quick overview of its recommendations and other content. The EIAO is to

write it when she or he has finished the analysis and made an enforcement recommendation. The purpose of the summary is to concisely lay out the principal findings of the FSA report in one place and is similar to a scientific journal article abstract. After reading the executive summary, the reader should understand the main regulatory findings that the EIAO has made and the evidence that supports those findings.

B. A good executive summary contains the following:

1. A sentence or two that describes the establishment (demographics) and its processes, including the major types of products it produces;
2. A sentence or two that describes the establishment's compliance history;
3. A couple of sentences that describe the major findings leading to the recommendation; and
4. A couple of sentences that discuss the EIAO's analysis of the significance of those findings under the regulations, and what they show about the establishment's ability to produce safe products.

NOTE: Remember that the purpose of the executive summary is to provide an overview of the FSA report for those who may not have time to read the whole report carefully.

C. The executive summary is to emphasize the EIAO's recommendation and include only the essential or most significant information to support that recommendation.

D. The EIAO is to organize the executive summary according to the sequence of information presented in the full report. This organization will support the coherence of the whole report.

E. A well constructed executive summary should be no more than 350 words and a maximum of 500 words for potentially complicated enforcement recommendations or FSAs documenting many HACCP processes. The EIAO is to make the summary concise and to ensure that it shows how he or she has arrived at the recommendation.

F. The EIAO should look at the first and last sentences of paragraphs in the final "Analysis" questions for each section since they often contain key pieces of information to start outlining the executive summary.

G. The EIAO may find it helpful to begin by writing a summary that includes whatever the EIAO thinks is important. Next, he or she should review the summary and edit out unnecessary words or repetitive sentences.

H. The EIAO is not to introduce into the Executive Summary any information that is not contained in the FSA report.

How can an EIAO know that she or he has included enough information in the executive summary?

A simple rule-of-thumb is to imagine that the summary is the only part of the FSA report that anyone can see and then ask the question:

Does this summary adequately explain and support the recommendation?

CHAPTER 14: DOCUMENTING THE FSA

How does the EIAO document his or her findings using the FSA tools and then submit those findings for posting?

A. The EIAO is to use the appropriate FSA tools, available on the Server and the Meat Inspection Office to document the findings during the FSA based on the HACCP processes employed by the establishment.

B. The EIAO is to download the appropriate FSA tools to his or her computer and document findings, as they are identified, at the start of each FSA. As explained previously, the EIAO is not to keep copious notes of findings outside the FSA tools as these notes can be considered evidence.

C. To ensure that the most current FSA tool is used, the EIAO is to download the appropriate FSA tools at the beginning of each FSA. The FSA tools are not static and change as necessary, so the EIAO needs to ensure that he or she is using the most current version of the FSA tools. The VT office is given the most up to date tools by the state federal relations office from FSIS.

D. The EIAO is to use the Demographics, Recommendation, and Background Tool to document the establishment's demographic information, recommendation, and background information.

E. The EIAO is to assemble the final report by placing the individual completed FSA tools, as separate files into a zip file folder. The EIAO is not to assemble the individual completed FSA tool questions into one document. The EIAO is to submit the draft FSA report to the SEIAO.

1. If no enforcement action results, the EIAO is to finalize the FSA report and post it within five working days of the conclusion of the exit conference.
2. If there is an enforcement action, the EIAO is to finalize the FSA report and post it within 48 hours of the conclusion of the exit conference.

CHAPTER 15: EXIT CONFERENCE

How does the EIAO schedule and conduct the exit conference?

A. Before holding an exit conference with the establishment, the EIAO is first to discuss his or her findings and recommendations with the SEIAO and with the appropriate DO leadership to ensure that all scientific, technical, and policy issues in the EIAO's report have been resolved. If consultation with Agency experts is needed, the Deputy District Manager (DDM) is to contact the assigned EARO to facilitate obtaining such input. Once there is agreement on the strategy, and the action to be taken, the EIAO is to meet with the FLS, IIC, and IPP to discuss the findings and the outcome of the FSA.

B. The EIAO is to correlate with the in-plant inspection team to ensure that any NRs are written, and any coordination among the group is arranged. NRs are to be issued at the exit conference.

C. Next, the EIAO is to schedule the exit conference. The EIAO is to invite establishment management to attend the exit meeting. Although it is strongly encouraged that the IIC also attend the exit conference, the exit conference should not be delayed too long to provide for their attendance. The EIAO is to document the date he or she held the exit conference and include this information in the FSA report using the [Demographics, Recommendation, and Background Tool](#).

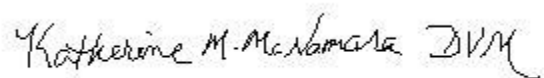
D. When the EIAO conducts the exit conference with establishment officials and any FSIS personnel who attend, the EIAO is to:

1. Thank the establishment for its cooperation;
2. Describe the FSA findings to the establishment, including any recommendations that the EIAO has made;
3. Describe the basis for all NRs being issued at the exit conference that are based on the FSA findings, as well as any enforcement recommendations that the EIAO has made. If there are any enforcement action documents available, they are to be given to the establishment at the exit conference;
4. Review the FSA report and provide a copy that is watermarked as "Draft" to establishment management and advise the establishment that a final copy of the FSA will be provided by the Meat Inspection Office.
5. Answer any questions that the establishment may have; and

6. Provide a business card with contact information to establishment and IPP so that they can contact the EIAO with technical questions, if necessary.

E. The EIAO is to direct the small and very small establishments to FSIS [compliance assistance resources](#) to meet the Agency's obligation related to the [Small Business Regulatory Enforcement and Fairness Act](#) (SBREFA).

Refer questions through supervisory channels.

A handwritten signature in black ink that reads "Katherine M. McNamara DVM". The signature is written in a cursive, flowing style.

Katherine M. McNamara, DVM
Head of Service - Meat Inspection Service